

A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device “nonthermal shortwave therapy” (SWT), was published on October 13, 2015. See here:

<https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to>

While the device submitted and cleared through K121702 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 6, 2013

OrthoCor Medical
% MEDIcept, Inc.
Mr. David Rothkopf
President
200 Homer Avenue
Ashland, MA 01721

Re: K121702

Trade/Device Name: OrthoCor Active Device
Regulation Number: 21 CFR 890.5290(b)
Regulation Name: Shortwave Diathermy for All Other Uses
Regulatory Class: Class III
Product Code: ILX
Dated: April 17, 2013
Received: April 18, 2013

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to:

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121702

Device Name: **OrthoCor Active Device**

Indications for Use:

The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

Prescription Use **X** 21CFR 801, Subpart D OR Over-the-Counter Use **_** 21 CFR 876.1500

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign Off
Office of Device Evaluation

Joyce M Whang -S

510 (K) _____

K121702

MAY 06 2013

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92(a)(1)
Date this 510(k) Summary was prepared: May 2, 2013

A) Manufacturer: OrthoCor Medical, Inc.
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80 8th Street
Minneapolis, MN 55402
Contact: John Dinusson

Contact: MEDIcept, Inc.
200 Homer Ave
Ashland, MA 01721
Telephone: 508-231-8824
Fax: 508-231-8861
Contact: F. David Rothkopf

B) Trade Name OrthoCor Active Device

Common Name: Shortwave Diathermy

Classification Name: Diathermy, Shortwave, For Use Other Than Applying Therapeutic Deep Heat.

Device Regulations: 21 CFR 890.5290(b)

Class: III

Product Code: ILX

C) Predicate: K091996 – OrthoCor Active Knee System

D) Device Description:

The OrthoCor General Use Device (marketed as the OrthoCor Active Device) is a portable (battery operated) non-invasive shortwave diathermy medical device. Through the use of resonators and two applicator coils, the device applies electromagnetic energy at a radio frequency (RF) of 27.12MHz for the treatment of medical conditions by means other than the generation of deep heat within body tissues, i.e., by athermal means. The OrthoCor General Use Device delivers the pulsed RF signal of $6.5 \pm 0.5 \mu\text{Ws/cm}^3$ to the tissue target via inductive coupling using two applicator coils. It is a general use device and can be positioned on the body with a wrap designed to hold the device in place at the location that requires treatment.

E) Intended Use:

The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

F) Substantial Equivalence Summary

	OrthoCor General Use Device	OrthoCor Active Knee System
	TBD	K091996
Indication for Use	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue	Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue
Exposure	30 minutes	30 minutes
Anatomical site	General Use	Knee
Clinical data submitted	No	No
Electrical Specifications		
Peak Power	0.5W	0.5W
Average Output Power (over 1 second)	2mW	2mW
Energy Density (μ)	6.5	6.5
Voltage	3V	3V
Therapy control burst width	2ms/PPR 2±.03Hz	2ms/PPR 2±.03Hz
Burst frequency	2Hz	2Hz
Duty Cycle (%)	0.4%	0.4%
Current	10mA	10mA
Frequency – short wave	27.12 MHz	27.12 MHz
Peal B Field (T)	0.004042 T*	0.004042 T*
Output impedance	50 Ohm	50 Ohm
Physical Specifications		
Applicator Size, Coil perimeter	108.6cm	108.6cm
Applicator Type	Induction coil	Induction coil

*Value calculated by: $B=\sqrt{u * 2\mu_0}$, u = Energy Density , μ_0 = Magnetic Constant = $4\pi * 10^{-7}$

G) Conformity to Standards

There were no FDA guidance documents identified for this device.

- IEC 60601-1 *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2 *Medical Electrical Equipment- Part 2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility- Requirements and Tests*

H) Performance Testing

The results of the bench and safety testing indicated that the new device is as safe and as effective as the predicate device. The energy/area is the most relevant measure because it is the total energy deposited into the body per specific area. The OrthoCor device and the predicate device all have similar energy/area measurements.

Conclusion

OrthoCor Medical, Inc. believes that based on the indications for use, technological characteristics, and comparison to predicate devices, the OrthoCor General Use Device has been shown to be substantially equivalent to the predicate and safe and effective for its intended use.